

REMARKS

I. Status of Claims

Claims 8-24, 26, and 31 are pending in this application. Claims 1-7 and 27-29 were canceled.

In the present Amendment, claims 25 and 30 have been cancelled without prejudice or disclaimer. Claims 9, 16, 17, 24, 26, and 31 have been amended solely to more clearly recite the invention. Support for the amendments is found in the specification, for example, in paragraphs [0149]-[0158]. Applicants have not introduced any new matter by the amendment, nor does the amendment raise new issues or necessitate the undertaking of any additional search of the art by the Examiner.

II. Obviousness-Type Double Patenting Rejection

The Examiner provisionally rejects claim 8 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of co-pending Application No. 10/715,556 ("the co-pending '556 application"). Office Action, page 3.

Solely to advance prosecution, Applicants filed a Terminal Disclaimer in the co-pending '556 application on July 25, 2006. Accordingly, Applicants respectfully request that this rejection be held in abeyance until allowable subject matter is indicated.

III. Rejection under 35 U.S.C. § 112, First Paragraph, Written Description

The Examiner rejects claims 9-15, 17-26, 30, and 31 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Office Action, page 4. Specifically, the Examiner alleges that the new provisos recited in claims 9 and

17, *i.e.*, provisos (2) and (3), are not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. *Id.* Applicants respectfully disagree with the Examiner and traverse this rejection for at least the following reason.

The compounds of formula (I), as described in the specification, include the compounds that were “provisoed out” in provisos (2) and (3), *i.e.*, 3-{4-(3,4,5-trimethoxyanilincarbonyl)-3-oxo-2,3-dihydropyridazine-6-yl}-2-phenyl-pyrazolo[1,5-a]pyridine; 3-{4-(N-ethoxycarbonylmethyl)-carbamoyl-3-oxo-2,3-dihydro-pyridazine-6-yl}-2-phenyl-pyrazolo[1,5-a]pyridine; 3-{4-(N-carboxymethyl)-carbamoyl-3-oxo-2,3-dihydro-pyridazine-6-yl}-2-phenyl-pyrazolo[1,5-a]pyridine; 6-(4-cyanophenyl)-4[(4-carboxybutyl)-aminocarbonyl]-2H-pyridazin-3-one; 6-(4-methoxyphenyl)-4-methylcarbamoyl-2H-pyridazin-3-one, and compounds of formula (I) wherein when A is $\text{NHCOCH}(\text{CH}_3)_2$, Ar is unsubstituted or at least monosubstituted bicyclic heteroaryl.

A limitation excluding species of a genus is sufficiently supported by an original specification that taught the entire genus, because the “specification, having described the whole, necessarily described the part remaining,” as well as the part being provisoed out. *See In re Johnson*, 194 USPQ 187, 196 (CCPA 1977). “It is for the inventor to decide what *bounds* of protection he will seek.” *Id.* (emphasis in original). Accordingly, Applicants respectfully request this rejection be withdrawn.

IV. Rejection under 35 U.S.C. § 112, First Paragraph, Enablement

The Examiner rejects claims 9-26 under 35 U.S.C. § 112, first paragraph, for lack of enablement. Office Action, pages 4-16.

A. Claims 9-16

The Examiner alleges that because claims 9-16 cover the inhibition of GSK-3 β or the phosphorylation of the Tau protein “in any patient,” the claims are not enabled. *Id.* at page 15 (emphasis in original). Applicants respectfully disagree. However, solely to advance prosecution, Applicants have amended claims 9 and 16 and respectfully submit that claims 9-16 as amended are fully enabled by the specification for at least the following reasons.

“The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.” M.P.E.P. § 2164.01. Further, “if the art is such that a particular model is recognized as correlating to a specific condition, then it should be accepted as correlating unless the examiner has evidence that the model does not correlate.” *Id.* § 2164.02.

Here, the originally-filed specification shows, under “Tau-phosphorylation” and “GSK-3 β ” in paragraphs [0306]-[0310], that the inventive compounds showed potency of inhibiting the phosphorylation of the tau-protein or the kinase GSK-3 β as indicated by the IC₅₀ values. The Examiner has failed to establish that this *in vitro* data is not recognized as correlating to *in vivo* inhibitory potency of GSK-3 β or the phosphorylation of the Tau protein. Therefore, contrary to the Examiner’s allegation, the specification has demonstrated that, coupled with the information known in the art, one of ordinary skill in the art would use the presently claimed compounds for inhibiting GSK-3 β or the phosphorylation of the Tau protein *in vivo* without undue experimentation.

As the Examiner has failed to point to any evidence rebutting the correlation between the inhibition of GSK-3 β or the phosphorylation of the Tau protein *in vitro* and *in vivo*, and as the Examiner's analysis of Wands factors in support of the lack-of-enablement rejection on pages 4-15 of the Office Action is directed to the method of treating various diseases, while claims 9-16 as currently amended recite a "method for inhibiting GSK-3 β or the phosphorylation of the Tau protein *in vivo*", this rejection is improper. Accordingly, Applicants respectfully request this rejection of claims 9-16 be withdrawn.

B. Claims 17-26

The Examiner also rejects claims 17-26 under 35 U.S.C. § 112, first paragraph, for lack of enablement. Office Action, pages 4-15. Specifically, the Examiner alleges that, by analyzing each Wands factor, one of ordinary skill in the art would not be able to practice the presently claimed invention without undue experimentation. *Id.* Applicants respectfully disagree.

However, solely to advance prosecution, claims 17, 24, and 26 have currently been amended as shown above. The Examiner admits that the specification is "enabling for the treatment of cranial and spinal traumas and peripheral neuropathies, obesity, types II diabetes, atherosclerotic cardiovascular diseases, essential hypertension, [and] polycystic ovary syndrome." Office Action, page 4. Therefore, Applicants respectfully request this rejection be withdrawn.

V. Objection

The Examiner objects to claims 17 and 24 because of the term "strokes." Office Action, page 16. This object is moot in view of the current amendments, deleting the term "strokes" in claims 17 and 24. Therefore, Applicants respectfully request this objection be withdrawn.

VI. Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this application, and the timely allowance of the pending claims.


If the Examiner believes a telephone conference would be useful in resolving any outstanding issues, the Examiner is invited to call the Applicants' undersigned representative at (202) 408-4218.

If there is any fee due in connection with the filing of this response, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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